

In the United States Court of Federal Claims

No. 20-1375

(Filed Under Seal: August 15, 2023)

Reissued: September 6, 2023¹

ROBERT ANTHONY SIMEONE, III, *as*
parent of R.S., a minor,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Robert Anthony Simeone, III, pro se, Savannah, TX, for petitioner.

Emilie Williams, Vaccine/Torts Branch, Civil Division, U.S. Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SMITH, Senior Judge

Petitioner, Robert Anthony Simeone, III, on behalf of his minor child, R.S., seeks review of a decision issued by Chief Special Master Brian H. Corcoran denying his petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 *et seq.* (the “Vaccine Act”), alleging that the diphtheria, tetanus, acellular-pertussis (“DTaP”) vaccine R.S. received on September 1, 2017, caused R.S. to suffer an acute encephalopathy shortly after receiving the vaccine. The Chief Special Master denied compensation, finding that petitioner did not establish a cognizable injury. Ruling on Entitlement, ECF No. 54, at 2 [hereinafter Entitlement Decision]. Petitioner now moves this Court to review the Entitlement Decision. For the reasons that follow, the Court **DENIES** petitioner’s Motion for Review.

I. BACKGROUND AND PROCEDURAL HISTORY

On May 21, 2016, R.S. was born prematurely by two months. *See* Petitioner’s Exhibit [hereinafter PX] 1, ECF No. 13. On September 1, 2017, R.S. received the DTaP vaccine, as well

¹ An unredacted version of this opinion was issued under seal on August 15, 2023. The parties were given an opportunity to propose redactions, but no such proposals were made.

as the haemophilus influenzae type B (“HiB”) and Hepatitis A (“Hep A”) vaccines. PX3 at 1; PX8 at 4–5. Petitioner recalled that R.S. was sick prior to receiving the vaccines. *See* Amended Petition, ECF No. 40 at 6, 28 [hereinafter Am. Pet.] (“At the very same appointment he was given the DTaP vaccine, R.S. was diagnosed with ‘bilateral otitis media’ (BOM) and a ‘viral syndrome.’”); *id.* at 7 (“R.S. was battling bilateral otitis media, requiring antibiotics, [and] a viral syndrome with a cough, requiring albuterol and budesonide . . .”). Within a few hours of vaccination, R.S. developed a fever. *Id.* at 12–13. R.S.’s parents did not seek immediate medical attention for R.S. *Id.* at 13–14. At some point during the next three days, R.S. allegedly experienced an acute encephalopathy that later resulted in chronic, autoimmune encephalitis and regressive encephalopathy that persists to this day. *Id.* at 12. However, petitioner provided no “medical records of an acute encephalopathy in the 72 hours following vaccine administration[.] In fact, *there are no medical records, whatsoever*, recorded during the 72 hours post-vaccination.” Petitioner’s Response to Order to Show Cause, ECF No. 39 at 2 (emphasis added).

On February 22, 2019 (eighteen months post-vaccination), R.S. was brought to developmental-behavioral pediatrician Fadiyla Dopwell, M.D. PX15 at 1. During the visit, R.S. was evaluated for developmental needs associated with premature birth, developmental delays, and social communication issues. *Id.* Dr. Dopwell provided R.S.’s parents with handouts and activities to promote developmental progress and referred them to websites for further information about autism spectrum disorder. *Id.* at 5. On May 10, 2019, R.S. was seen again by Dr. Dopwell, and she made similar clinical observations to the February 22, 2019, visit. PX16 at 1–5.

On September 30, 2019, R.S.’s parents sought a genetics consultation from Rachel Lombardo, M.D., at the Children’s Dallas Genetic/Metabolic/Down Syndrome Clinic. PX55 at 3–5, 11. R.S. was reportedly referred to Dr. Lombardo because of “global delays and concern for possible autism spectrum disorder.” *Id.* at 3. The main goal of the visit was allegedly to obtain methylenetetrahydrofolate reductase (“MTHFR”) testing “to diagnose potential genetic differences.” *Id.* Dr. Lombardo ultimately did not recommend MTHFR testing for R.S. *Id.* at 6. On January 27, 2020, R.S.’s parents sought medical assistance for R.S. from an integrative medicine family practitioner, Kenneth Bock, M.D. PX29 at 5–6. Dr. Bock evaluated R.S. and diagnosed him with suspected neuroimmune disorder and regressive encephalopathy. *Id.* at 7. In May 2020, R.S. was seen again by Dr. Bock for a range of treatments. *See id.* at 22–27. Presently, R.S.’s symptoms remain largely unchanged. Am. Pet. at 12. None of R.S.’s treating physicians concluded that R.S. sustained an encephalopathy associated with the September 1, 2017, DTaP vaccine. *See* Entitlement Decision at 3 n.4.

On or around September 1, 2020, the applicable three-year statute of limitations period expired. 42 U.S.C. § 300aa-16(a)(2) (“[N]o petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom . . .”). On October 13, 2020, petitioner filed a Petition with the Office of Special Masters, amended on April 12, 2022, seeking compensation for vaccine-related injuries. *See generally* Petition, ECF No. 1; *see also* Am. Pet. at 40. On September 14, 2021, respondent filed its Motion to Dismiss, arguing exclusively that petitioner’s Petition was untimely. *See* Respondent’s Motion to Dismiss, ECF No. 29. On January 6, 2022, Chief Special Master Brian H. Corcoran deferred ruling on the timeliness of petitioner’s claim and ordered the parties to file

supplemental briefs regarding the merits of petitioner's claim. *See* January 6, 2022 Order, ECF No. 36.

On February 24, 2023, the Chief Special Master dismissed petitioner's claim, finding that petitioner failed to establish that R.S. suffered a compensable injury.² *See* Entitlement Decision at 2. On March 24, 2023, petitioner filed a Motion for Review of Chief Special Master Corcoran's decision with this Court. *See* Petitioner's Motion for Review, ECF No. 55 [hereinafter Pet.'s MFR]. On April 24, 2023, respondent filed its Response to petitioner's Motion for Review. *See* Respondent's Response to Petitioner's Motion for Review, ECF No. 59 [hereinafter Resp. to MFR]. Petitioner's Motion is fully briefed and ripe for review.

II. STANDARD OF REVIEW

Under the Vaccine Act, this Court may review a Special Master's decision upon the timely request of either party. 42 U.S.C. § 300aa-12(e)(1)–(2). In reviewing such a request, this Court may:

- (A) uphold the findings of fact and conclusions of law . . . ,
- (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or
- (C) remand the petition to the special master for further action in accordance with the court's direction.

Id. § 300aa-12(e)(2)(A)–(C). “Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the ‘not in accordance with law’ standard; and discretionary rulings under the abuse of discretion standard.” *Munn v. Sec’y of Dep’t of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

When reviewing a special master's decision, this Court cannot “substitute its judgment for that of the special master merely because it might have reached a different conclusion.” *Snyder ex rel. Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009). This Court does not “reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder.” *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011) (citing *Broekelschen v. Sec’y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)). “[R]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.” *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotations and citation omitted). “[A]s long as a special master's finding of fact is ‘based on evidence in the record that [is] not wholly

² The Chief Special Master did not decide whether petitioner's claim was untimely nor whether the applicable limitations period was tolled. Ruling on Entitlement at 12 n.8, ECF No. 54. In any case, the timeliness of petitioner's claim is not on review at this Court.

implausible, we are compelled to uphold that finding as not being arbitrary or capricious.” *Porter*, 663 F.3d at 1249 (quoting *Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

III. DISCUSSION

Petitioner argues that he presented sufficient evidence to establish that R.S. suffered an injury—a Table encephalopathy, or an off-Table autoimmune encephalitis leading to developmental regressions—under the Vaccine Act. *See* Pet.’s MFR at 1–2. Specifically, petitioner argues that his testimonial evidence in the form of text messages and cell phone videos should be considered sufficient contemporaneous evidence of R.S.’s encephalopathy in the absence of medical records. *See id.* at 2–6. Petitioner further argues that he should be given a hearing where he may present his arguments. *See id.* at 14. In response, respondent argues that the Chief Special Master correctly found that petitioner failed to present sufficient evidence that R.S. suffered a Table encephalopathy, or an off-Table autoimmune encephalitis leading to developmental regressions. *See* Resp. to MFR at 7. Respondent further argues that a “Special Master in a Vaccine Act case has broad discretion to determine whether a fact or entitlement hearing is necessary to evaluate testimony, and the Act and the Vaccine Rules expressly authorize a Special Master to resolve a case without such hearings.” *Id.* at 10. For the reasons discussed below, the Court is inclined to agree with respondent.

A. Injury Requirement

Petitioners seeking recovery under the Vaccine Act must establish that a vaccine caused the injury at issue. The Vaccine Act provides that such causation is established through (1) a statutorily prescribed presumption of causation when the injury falls under the Vaccine Injury Table (“Table injury”); or (2) proof of causation-in-fact when the injury is not listed in the Vaccine Injury Table (“off-Table injury”). *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (internal citations omitted). To prove causation-in-fact, a petitioner must

show by preponderant evidence that the vaccination brought about [petitioner’s] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. (citing 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I)).

However, as a prerequisite to establishing causation, a petitioner must show that a cognizable injury actually occurred. *See Broekelschen*, 618 F.3d at 1346 (“[I]dentifying the injury is a prerequisite to the [*Althen*] analysis.”); *see also Lombardi v. Sec’y of Health & Hum. Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011) (“In the absence of a showing of the very existence of any specific injury of which the petitioner claims, the question of causation is not reached.”). A petitioner must demonstrate more than a “symptom or manifestation of an unknown injury.” *Lombardi*, 656 F.3d at 1353. Additionally, the Vaccine Act is clear that compensation may not

be awarded on the basis of petitioner’s contentions alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1); *see Cucuras v. HHS*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (“The Vaccine Act expressly bars the court or a special master from finding a table injury ‘based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion.’” (quoting 42 U.S.C. § 300aa-13(a)(1))).

The Chief Special Master’s finding that petitioner failed to present sufficient evidence that R.S. suffered a compensable injury for a Table or non-Table claim was not arbitrary, capricious, an abuse of discretion, or contrary to law. Reviewing petitioner’s assertions of a Table encephalopathy, the Chief Special Master wrote the following:

Table claimants seeking to prove a vaccine-caused encephalopathy must establish *both* that the injured party experienced an “acute” encephalopathy—typically evidenced by a decreased change in consciousness . . . of sufficient severity to warrant hospitalization—and that the encephalopathy subsequently became “chronic” (that is, it lasted for at least six months). The acute encephalopathy must manifest within three days/seventy-two hours, and if alleged to have been experienced by a child less than eighteen months old, must be “indicated by a significantly decreased level of consciousness that lasts at least 24 hours.”

Entitlement Decision at 11 (emphasis in original) (internal citations omitted). For a non-Table encephalopathy, the Chief Special Master explained that the claims must be supported by preponderant evidence, and “that evidence must establish *more* than simply a subsequent neurologically-derived symptom (since virtually any injury impacting the brain could be deemed *some* form of encephalopathy).” Entitlement Decision at 11 (emphasis in original).

Here, the Chief Special Master found that petitioner had neither (1) presented any medical records establishing an encephalopathy within seventy-two hours of vaccination, as required for a Table claim, nor (2) presented any medical records to prove causation-in-fact for an off-Table claim. *Id.* at 13; 42 C.F.R. § 100.3. Indeed, the petitioner plainly acknowledged that he did not provide medical records for the critical time frame at issue. *See* Pet.’s MFR at 4 (stating that the contemporaneous text messages and cell phone videos “provide evidence for a time period when there are no medical records at all”); Entitlement Decision at 4–5 (“Petitioner . . . acknowledges that he can point to no medical records establishing an acute encephalopathy occurred in [the 72-hours-post-vaccination] timeframe.”). The Chief Special Master found that petitioner had only provided “personally-generated” contemporaneous evidence, such as text messages and cell phone videos produced by petitioner and his family, to establish that R.S. experienced the claimed injury. Entitlement Decision at 12–14. The Chief Special Master concluded that this evidence was insufficient to show that a compensable injury occurred. *See id.* at 13 (“An encephalopathy is a particularly acute injury, and it must have some record substantiation—meaning *medical* evidence that the allegedly-harmed child was so severely ill that medical treatment was sought. Otherwise, it is beyond speculative to assume that regression or other post-vaccination developmental issues are due to the vaccine”) (emphasis in original). The Chief Special Master also noted that petitioner’s submitted records suggest an alternative explanation for the alleged injury: a possible diagnosis of autism spectrum

disorder. *Id.* at 14 n.9 (“[I]t appears treaters have directly diagnosed, or at least considered, an autism spectrum disorder as explanatory [of R.S.’s developmental changes].”).

The Chief Special Master reviewed the evidence under the Vaccine Act’s injury requirement and concluded that petitioner did not meet his evidentiary burden. The Vaccine Act is clear that compensation may not be awarded on the basis of petitioner’s contentions alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1); *see Cucuras*, 993 F.2d at 1528 (“The Vaccine Act expressly bars the court or a special master from finding a table injury ‘based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion.’” (quoting 42 U.S.C. § 300aa-13(a)(1))). This Court does not “reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder.” *Porter*, 663 F.3d at 1249 (citing *Broekelschen*, 618 F.3d at 1349). The Court concludes that the Chief Special Master considered the evidence in the record, drew plausible inferences, and articulated a rational basis for his decision. *See Lampe*, 219 F.3d at 1360. Accordingly, the Court finds that the Chief Special Master’s conclusion—that petitioner did not establish a cognizable injury—was not arbitrary, capricious, an abuse of discretion, or contrary to law.

B. Dismissal of Petition Without Hearing

The Vaccine Act states that a special master “may conduct such hearings as may be reasonable and necessary,” 42 U.S.C. § 300aa-12(d)(3)(B)(v), giving special masters “wide discretion in conducting the proceedings in a case,” *Burns v. Sec’y of Dep’t of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). The Vaccine Act permits a special master to decline to hold an evidentiary hearing. *See Kreizenbeck v. Sec’y of Health & Hum. Servs.*, 141 Fed. Cl. 138, 139 (2018) (“[S]pecial masters are not obligated to hold an evidentiary hearing before issuing an opinion.”). The Vaccine Rules were promulgated so as to not require the “routine use of oral presentations, cross examinations, or hearings.” *Id.* at 139–40 (citing 42 U.S.C. § 300aa-12(d)(2)(D)). If the special master affords a party “a full and fair opportunity to present its case,” it is permissible to proceed with a ruling on the record. *Spahn v. Sec’y of Health & Hum. Servs.*, 133 Fed. Cl. 588, 600 (2017).

The Chief Special Master acted within his discretion when he decided to proceed without a hearing. The Chief Special Master was not obligated to hold an evidentiary hearing but provided an explanation for this decision to forego a hearing in this case. *See* Entitlement Decision at 14–15 (stating that based on the record evidence, “it would be an unnecessary expenditure of judicial resources to continue the case (no matter how heartfelt Petitioner’s good-faith desire to maintain the case might be)”). Importantly, the Chief Special Master gave petitioner a full and fair opportunity to prove his claim. *See* ECF Nos. 11, 16 (extensions of time to file affidavits and medical records); ECF No. 36 (Order to Show Cause). The Chief Special Master weighed the entire evidentiary record before him and concluded that petitioner failed to provide any medical records or expert medical opinion supporting the assertion that R.S. sustained the claimed injury within a reasonable timeframe following receipt of the September 1,

2017, vaccine.³ See Entitlement Decision at 14–15. In any event, petitioners are not entitled to an evidentiary hearing as of right. See *Caron v. Sec’y of Health & Hum. Servs.*, 136 Fed. Cl. 360, 386 (2018) (internal citations omitted). Thus, the Chief Special Master acted within his discretion when he decided to proceed without a hearing.

IV. CONCLUSION

For the foregoing reasons, the Court concludes that the Chief Special Master did not act arbitrarily, capriciously, or contrary to law, nor abused his discretion. Accordingly, the Court upholds the Chief Special Master’s decision and **DENIES** petitioner’s Motion for Review.

IT IS SO ORDERED.

s/ *Loren A. Smith*

Loren A. Smith,
Senior Judge

³ On March 24, 2023, petitioner introduced, for the first time, additional exhibits for this Court’s consideration. See Petitioner’s Motion For Review at 14–18, ECF No. 55; Petitioner’s Exhibits 75–82, ECF No. 56. However, Vaccine Rule 8(f)(1) provides that “[a]ny fact or argument not raised specifically in the record before the special master will be considered waived and cannot be raised by either party in proceedings on review of a special master’s decision.” R. Ct. Fed. Cl., App. B, 8(f)(1). Thus, this Court cannot consider exhibits introduced by petitioner for the first time in his Motion for Review.